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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,235	09/29/2003	Danila Fava	6584	2659

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EXAMINER	
LAMM, MARINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,235	FAVA ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19-25* is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/02; 6/17/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 are pending in this application filed 9/23/03, which is a 371 of PCT Application No. PCT/IT00/00309, filed 07/27/2000, which claims priority to the Italian Application No. RM99A000465 filed 07/21/99. Acknowledgment is made of the preliminary amendment filed 1/18/02.

Priority

1. This application filed under 35 USC 371 lacks the specific reference to the earlier applications in the first sentence of the specification or in an application data sheet. The Applicant is invited to amend the specification to include a statement referring to the earlier filed PCT and/or foreign applications.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is viewed as indefinite because it recites the limitation "in **the** suitable polymer" in line 2. There is no antecedent basis for this limitation in the

claim. It is suggested that the Applicants use the language "in **a** suitable polymer".

Claim 11 is viewed as indefinite because it recites the limitation "from about 0.01% to 10%", which is not within the concentration range of Claim 10 ("from about 0.05% to 20%"), from which it depends. There is no antecedent basis for the limitation "from about 0.01% to 10%" in Claim 11.

4. Claims 2-18 are rejected because they contain all the limitations of Claim 1 rejected for the reasons given above.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-7 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zook (US 5,167,649) in view of either Gueret (US 6,419,935) or Fox et al. (US 5,405,366).

a. Zook in view of Gueret

Zook teaches drug delivery systems for the removal of dermal lesions such as warts, actinic keratoses and superficial tumors, such systems comprised of a

polymeric carrier (patch) and one or more of the active ingredients, including salicylic acid (2-hydroxybenzoic acid) and trichloracetic acid, incorporated therein. See col. 3, lines 18-62; Claim 3. The Zook reference does not teach menthol ((1α, 2β, 5α)-5-methyl-2-(1-methylethyl)cyclohexanol)) of the instant claims. However, Gueret teaches using menthol for providing "skin with a feeling of freshness" in cosmetic patches. See col. 7, lines 23-29. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook such that to employ menthol. One having ordinary skill in the art would have been motivated to do this to obtain fresh feel of the formulations as suggested by Gueret. Further, with respect to Claim 2, Zook does not teach the polymers of the instant claim. However, Gueret teaches using PVA in cosmetic patches as a water-absorbing compound. See col. 7, lines 5-6. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook such that to employ PVA. One having ordinary skill in the art would have been motivated to do this to obtain water-absorbing effect as suggested by Gueret.

b. Zook in view of Fox et al.

Zook applied as above. The reference does not teach menthol of the instant claims. However, Fox et al. teach using menthol in adhesive patches as a topical counter-irritant. See col. 20, lines 9-15. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the

invention was made to modify the compositions of Zook such that to employ menthol. One having ordinary skill in the art would have been motivated to do this to obtain a counter-irritant effect as suggested by Fox et al. Further, with respect to Claim 2, Zook does not teach the polymers of the instant claim. However, Fox et al. teach using biocompatible low molecular weight polyethylene glycols as humectants in patches useful for delivery pharmacologically active agents. See col. 7, lines 9-15. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook such that to employ biocompatible low molecular weight polyethylene glycols. One having ordinary skill in the art would have been motivated to do this to obtain a humectant effect as suggested by Fox et al.

With respect to Claims 4-7, Zook does not explicitly teach the claimed concentrations of trichloracetic acid or salicylic acid. However, the determination of optimal or workable concentration of either ingredient by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired keratolytic effect of the composition.

With respect to Claims 13-17, the recitation of the intended use of the composition is not given any patentable weight. The courts have held that in composition claims "intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." See *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963)

7. Applicant cannot rely upon the foreign priority papers to overcome the rejection over the Gueret reference because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

8. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zook (US 5,167,649) in view of either Gueret (US 6,419,935) or Fox et al. (US 5,405,366) and further in view of either Zaffaroni (US 3,734,097) or Wise et al. (US 5,977,176).

c. Zook in view of either Gueret or Fox et al. and further in view of Zaffaroni.

Zook in view of either Gueret or Fox et al. applied as above. Neither reference teaches the corticosteroids of the instant claims. However, Zaffaroni teaches using anti-inflammatory steroids, including cortisone, hydrocortisone and triamcinolon, to prevent reddening of the "normal" skin surrounding the skin lesion, to which an adhesive patch is applied. See col. 8, lines 3-16. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook in view of either Gueret or Fox et al. such that to employ an anti-inflammatory steroid such as cortisone, hydrocortisone or triamcinolon. One having ordinary skill in the art would have been motivated to do this to protect the skin surrounding the lesion,

to which the patch is applied, from inflammation and reddening as suggested by Zaffaroni.

d. Zook in view of either Gueret or Fox et al. and further in view of Wise et al.

Zook in view of either Gueret or Fox et al. applied as above. Neither reference teaches the corticosteroids of the instant claims. However, Wise et al. teach using anti-inflammatory corticosteroids such as hydrocortisone or triamcinolon, in combination with salicylic acid, for the topical wart treatment. See col. 3; col. 5, lines 11-27. Triamcinolon can be used in concentrations of 0.1% to 0.5%. See col. 5, lines 11-15. The topical compositions of Wise et al. "relieve the discomfort due to the inflammation", which includes pain, redness, swelling and itching of the lesion. See col. 3, lines 49-65. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook in view of either Gueret or Fox et al. such that to employ an anti-inflammatory steroid such as hydrocortisone or triamcinolon. One having ordinary skill in the art would have been motivated to do this to relieve discomfort associated with inflammation as suggested by Wise et al.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zook (US 5,167,649) in view of either Gueret (US 6,419,935) or Fox et al. (US 5,405,366) and further in view of Partain, III. et al. (US 4,946,870) and Taylor et al. (US 5,869,104).

Zook in view of either Gueret or Fox et al. applied as above. Neither reference teaches ethanol and sodium chloride of the instant claims. However, Partain, III. et al. teach using ethanol as a solvent for salicylic acid. See col. 9, line 65; col. 10, line 12; col. 15, Example 17. Further, Taylor et al. teach using sodium chloride for treating skin conditions, including warts. See Abstract; Claims. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook in view of either Gueret or Fox et al. such that to employ ethanol. One having ordinary skill in the art would have been motivated to do this to solubilize salicylic acid as suggested by Partain, III. et al. Further, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Zook in view of either Gueret or Fox et al. such that to employ sodium chloride. One having ordinary skill in the art would have been motivated to do this to obtain an additional wart-treating effect as suggested by Taylor et al.

Allowable Subject Matter

10. Claims 19-25 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter: Claims 19-25 are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed method of making a pharmaceutical composition.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 98/53822; US 3,814,095; US 4,250,193; US 5,476,664.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
11/9/05

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER